Exhibit 2

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

FEDERAL TRADE COMMISSION and

THE PEOPLE OF THE STATE OF NEW YORK, by LETITIA JAMES, Attorney General of the State of New York,

Plaintiffs,

v.

QUINCY BIOSCIENCE HOLDING COMPANY, INC., a corporation;

QUINCY BIOSCIENCE, LLC, a limited liability company;

PREVAGEN, INC., a corporation d/b/a/ SUGAR RIVER SUPPLEMENTS;

QUINCY BIOSCIENCE MANUFACTURING, LLC, a limited liability company; and

MARK UNDERWOOD, individually and as an officer of QUINCY BIOSCIENCE HOLDING COMPANY, INC., QUINCY BIOSCIENCE, LLC, and PREVAGEN, INC.,

Defendants.

Case No. 1:17-cv-00124-LLS

DEFENDANTS' TRIAL BRIEF

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Pursuant to Judge Stanton's Individual Practices and the Orders of this Court, dated November 23, 2021 and August 2, 2022 (Dkts. 234, 289), Defendants Quincy Bioscience Holding Company, Inc., Quincy Bioscience, LLC, Prevagen, Inc., Quincy Bioscience Manufacturing, LLC (collectively, "Quincy"), and Mark Underwood (together with Quincy, "Defendants") respectfully submit this Trial Brief to address the key legal and evidentiary issues that they anticipate will arise at trial.

INTRODUCTION

In this action, Plaintiffs the Federal Trade Commission ("FTC") and New York Attorney General ("NYAG") (the FTC and NYAG are collectively referred to as "Plaintiffs") seek to permanently enjoin Defendants from making certain marketing claims regarding the dietary supplement product, Prevagen®, under New York and federal law, and the NYAG seeks to recover monetary relief and civil penalties under New York law. As set forth herein and in Defendants' pending motion for summary judgment, Plaintiffs have failed to satisfy their burden required to obtain any of their requested relief.

Through this action, Plaintiffs seek to craft a new definition of the "competent and reliable scientific evidence" standard that has traditionally governed false advertising claims involving dietary supplement products. Plaintiffs' newfound standard is being applied uniquely against Quincy and is divorced from the FTC's own published guidance to industry (Dietary Supplements: An Advertising Guide for Industry" (the "FTC Guidance," Dkt. 222-6).) Apparently, Plaintiffs believe that they have full discretion to re-define the standard to suit their legal position.

For over 20 years, the FTC Guidance has required that structure-function claims be substantiated by "competent and reliable scientific evidence," which is a "flexible" standard that considers the "totality of the evidence" including, but not limited to, *in vitro* studies, animal

studies, human research, and epidemiological evidence. Since its inception, this framework has been guiding dietary supplement companies (including Quincy).

In this case, however, Plaintiffs attempt to abandon this longstanding "flexible" framework in favor of an amorphous standard to be applied without any predictability, hindering any company's ability to meaningfully ensure compliance. Plaintiffs have made the inexplicable assertion that "*in this case*," "competent and reliable scientific evidence" means something other than what the FTC Guidance says, and can *only* be established by "randomized, controlled human clinical studies ("RCTs") that are well-designed, well-conducted, and properly analyzed according to standards generally accepted by experts in the relevant field." In other words, Plaintiffs are essentially attempting to impose a drug-level substantiation standard and abolish the regulatory distinction between drugs and dietary supplements.

At trial (if necessary), Defendants will establish that they do in fact possess "competent and reliable scientific evidence" to substantiate all of the Challenged Claims, which meets the flexible standard set forth in the FTC Guidance *and* the more stringent standard that Plaintiffs propose for "this case." In addition to a series of *in vitro*, animal, and human clinical studies on apoaequorin and substantial scientific literature involving vitamin D (both active ingredients in Prevagen), Quincy also conducted a "gold standard" RCT examining the effects of apoaequorin on cognitive function in older adults—exactly what Plaintiffs purportedly require Quincy to demonstrate "in this case," and far more substantial than what is common or required in the dietary supplement industry.

Defendants' experts—whose expertise range a spectrum of relevant specialties, including internal medicine, nutrition, neuroscience, dietary supplement substantiation, pharmacology, epidemiology, and biostatistics—evaluated this substantiation in accordance with their own

professional judgment and standards in the relevant fields and the flexible, totality-of-the-evidence approach set forth in the FTC Guidance. All concluded that the Challenged Claims are supported by competent and reliable scientific evidence. While Plaintiffs and their experts attempt to minimize the import of the conclusions of Defendants' experts, they do so in a vacuum, by failing to acknowledge the extent of Defendants' scientific substantiation and—most glaringly—without even considering the standard set forth in the FTC Guidance.

STATEMENT OF THE CASE

I. FACTUAL BACKGROUND

Prevagen is a dietary supplement. The Prevagen line of products include Prevagen Regular Strength, Extra Strength Prevagen, and Prevagen Professional. Apoaequorin, one of Prevagen's active ingredients, is a calcium-binding protein derived from aequorin, which was originally discovered in the aequorea victoria jellyfish. In or around 2016, the Prevagen Products were reformulated to include 50 micrograms of vitamin D3 (in addition to apoaequorin) per capsule or chewable tablet, which is equivalent to 2000 IU of vitamin D. Prevagen's target market is, and always has been, healthy, older community-dwelling adults who are cognitively normal or who have mild cognitive impairment due to the normal aging process.

Plaintiffs allege that Defendants make the following marketing claims for Prevagen, and that such claims are false, misleading or unsubstantiated: that Prevagen (1) improves memory; (2) improves memory within 90 days; (3) reduces memory problems associated with aging; (4) provides other cognitive benefits, including but not limited to, healthy brain function, a sharper mind, and clearer thinking; and (5) is clinically shown to have such effects (the "Challenged Claims"). (Dkt. 1 ¶¶ 36, 39, 42, 44.)

None of these marketing claims are currently being disseminated in the manner alleged in the Complaint. In fact, Quincy stopped disseminating many of the marketing claims and

advertisements referenced in the Complaint even before it was filed. Further, on June 22, 2020, Quincy entered into a nationwide class action settlement in *Collins, et al. v. Quincy Bioscience, LLC*, No. 1:19-CV-22864 (S.D. Fla.) resolving a series of class action lawsuits challenging the same marketing claims at issue in this Action (the "*Collins* Settlement"). (Dkt. 224 ¶ 40.) As part of the *Collins* Settlement, Quincy agreed to include one of two statements (the "Qualifiers") when making the Challenged Claims:

> i. Based on a clinical study of subgroups of individuals who were cognitively normal or mildly impaired. This product is not intended to diagnose, treat, cure, or prevent any disease.
>
> ii. Based on results from two subgroups of individuals who participated in a randomized double blind placebo controlled clinical study. Participants in the two subgroups were cognitively normal or mildly impaired. This product is not intended to diagnose, treat, cure, or prevent any disease.

(*Id.*; Dkt. 222-34 at 7-8.) In November 2020, the terms of the *Collins* Settlement were approved by the district court reviewing the settlement and reduced to a final judgment upon the court's finding that said terms were "fair and reasonable." (Dkt. 222-36.) Defendants have since incorporated the Qualifiers into their advertising for Prevagen and have no intention of disseminating the Challenged Claims without the Qualifiers in the future. (Dkt. 224 ¶¶ 44-45.)

II. REGULATORY BACKGROUND FOR DIETARY SUPPLEMENT PRODUCTS

In passing the Dietary Supplement Health Education Act of 1994 ("DSHEA"), Congress recognized the benefits of dietary supplements and made clear that dietary supplements could be sold without being subject to the same stringent regulations required for drugs. *See* S. Rep. 103-410, at 24 (1994) ("[T]he scientific evidence supporting a claim [with respect to a dietary supplement] should not be held to the same standard used in evaluating new drug applications."); S. 784, 103rd Cong. § 2(b)(2)(B) (1994) ("It is the purpose of [the DSHEA] to . . . clarify that . . . dietary supplements should not be regulated as drugs."); 21 U.S.C. § 321(g)(1).

DSHEA created a new category of marketing claims called structure/function claims, which "describe[] the role of a nutrient or dietary ingredient intended to affect the structure or function in humans." 21 U.S.C. § 343(r)(6)(A). Structure/function claims must be "truthful and not misleading" and, unlike drug claims, do not require the prior approval of FDA. *See* 21 U.S.C. §§ 321(g)(1), 343(r)(6). According to FDA guidance, structure/function claims include claims associated with "mild memory loss associated with aging." (Dkt. 222-10.)

In response to DSHEA, the FTC issued the FTC Guidance in an attempt to answer the "many questions" DSHEA generated "about the FTC's approach to dietary supplement advertising." *See United States v. Bayer Corp.*, No. 2:07-CV-00001, 2015 WL 5822595, at *3 (D.N.J. Sept. 24, 2015) (because "DSHEA does not specify what substantiation is necessary to render a claim 'truthful and not misleading,'" the FTC subsequently issued the FTC Guidance to shed further light on the meaning of "competent and reliable scientific evidence."); (Dkt. 222-6 at 1.) The FTC Guidance reiterates DSHEA's requirement that structure/function claims be "truthful, not misleading, and substantiated," and is specifically directed to dietary supplement manufacturers to "explain[] the how-tos of making sure your claims have appropriate scientific support." (Dkt. 221 ¶¶ 60, 61, 64.) Accordingly, as long as a dietary supplement product is not marketed as a drug, it is not regulated like a drug. (Dkt. 222-6 at 9-18; 21 U.S.C. § 343(r)(6); 21 U.S.C. §§ 321(g)(1).) As set forth below, both of Plaintiffs' claims in this case are governed by the substantiation standard set forth in the FTC Guidance.

III. PLAINTIFFS' CLAIMS

Plaintiffs commenced this action by filing a complaint on January 9, 2017. (Dkt. 1.) The FTC brings this action pursuant to Section 13(b) of the Federal Trade Commission Act, (*id.* ¶ 1) which authorizes the FTC to seek injunctive relief in federal court in limited circumstances when it "has reason to believe":

> (1) that any person is violating, or is about to violate, any provision of law enforced by the Federal Trade Commission, and
>
> (2) that the enjoining thereof pending the issuance of a complaint by the Commission and until such complaint is dismissed by the Commission or set aside by the court on review, or until the order of the Commission made thereon has become final, would be in the interest of the public—
>
> the Commission by any of its attorneys designated by it for such purpose may bring suit in a district court of the United States to enjoin any such act or practice. Upon a proper showing that, weighing the equities and considering the Commission's likelihood of ultimate success, such action would be in the public interest, and after notice to the defendant, a temporary restraining order or a preliminary injunction may be granted without bond: *Provided, however*, That if a complaint is not filed within such period (not exceeding 20 days) as may be specified by the court after issuance of the temporary restraining order or preliminary injunction, the order to injunction shall be dissolved by the court and be of no further force and effect: *Provided further*, That in proper cases the Commission may seek, and after proper proof, the court may issue, a permanent injunction. . . .

15 U.S.C. § 53(b). Here, the FTC seeks to enjoin alleged violations of Sections 5 and 12 of the FTC Act.[1] (Dkt. 1 ¶ 1.) Section 5 requires the FTC to prove "(1) a representation, omission, or practice, that (2) is likely to mislead consumers acting reasonably under the circumstances, and (3) . . . is material." *FTC v. Med. Billers Network, Inc.*, 543 F. Supp. 2d 283, 303 (S.D.N.Y. 2008) (citation omitted). Similarly, Section 12 requires the FTC to establish that Quincy's advertisements are "misleading in a material respect." 15 U.S.C. §§ 52(a)(2), 55(a)(1); *see also FTC v. Quincy Bioscience Holding Co., Inc.*, 272 F. Supp. 3d 547, 552-53 (S.D.N.Y. 2017).

The NYAG brings this action against Quincy[2] pursuant to New York Executive Law § 63(12) and New York General Business Law ("GBL") §§ 349 and 350. (Dkt. 1 ¶ 2.) To establish that the Challenged Claims violate the GBL, the NYAG must establish that Quincy "engaged in (1) consumer-oriented conduct that is (2) materially misleading and that (3) plaintiff suffered

[1] The FTC's request for monetary relief has been dismissed. (Dkt. 184.)

[2] The NYAG's claims against Underwood were dismissed. (Dkt. 272.)

injury as a result of the allegedly deceptive act or practice." *Koch v. Acker, Merrall & Condit Co.*, 18 N.Y.3d 940, 941 (2012) (citation omitted). GBL Sections 349 and 350 "comprise a 'mini' [FTC] Act, having been modeled on that analogous federal statute." *Braynina v. TJX Cos., Inc.*, No. 15-CV-05897, 2016 WL 5374134, at *6 (S.D.N.Y. Sept. 26, 2016) (alteration in original) (citing *People ex rel. Spitzer v. Applied Card Sys., Inc*., 11 N.Y.3d 105, 120 (2008)). They were "enacted 'to follow in the steps of the [FTC] with respect to the interpretation of deceptive acts and practices outlawed in Section 5 of the [FTC] Act.'" *Id.* (quoting *State ex rel. Lefkowitz v. Colo. State Christian Coll. of Church of Inner Power, Inc.*, 346 N.Y.S.2d 482, 486-87 (Sup. Ct., N.Y. Cnty. 1973)). Section 63(12) of the Executive Law "does not create an independent cause of action" but, rather, "is only a mechanism by which a petitioner may show that injunctive relief and restitution are proper in the event that the petitioner establishes that a respondent violated other statutes." *People ex rel. Schneiderman v. One Source Networking, Inc.*, 125 A.D.3d 1354, 1356 (4th Dep't 2015).

In the Complaint, both Plaintiffs sought a permanent injunction, rescission or reformation of contracts, restitution, the refund of monies paid, and the disgorgement of ill-gotten gains, and the NYAG further sought an award of civil penalties.

IV. PROCEDURAL HISTORY

On September 28, 2017, this Court granted Defendants' motion to dismiss, and found that "the Madison Memory Study followed normal well-accepted procedures, conducted a 'gold standard' double blind, placebo controlled human clinical study using objective outcome measures" and therefore "plaintiffs' challenge never proceeds beyond the theoretical." *Quincy Bioscience*, 272 F. Supp. 3d at 553. The Second Circuit remanded the action on February 21, 2019. (Dkt. 50.)

On September 17, 2021, the Court dismissed the FTC's claim for monetary relief, pursuant to the Supreme Court's decision in *AMG Capital Management, LLC v. Federal Trade Commission*, 141 S. Ct. 1341 (2021). (Dkt. 184.) More recently, the Court granted Defendant Mark Underwood's motion for partial summary judgment and dismissed the NYAG's claims against him for lack of personal jurisdiction, and denied the NYAG's cross-motion for summary judgment. (Dkt. 272.) The Parties await the Court's disposition of Defendants' summary judgment motion (Dkts. 220—228, 254—261, 278—281) and the parties' respective *Daubert* motions (Dkt. Nos. 302—308, 313—316, 318—321).

V. CONTESTED ISSUES OF LAW

A. Plaintiffs Failed to Identify or Prove Any Marketing Claims Other Than the Ones Expressly Identified in Their Complaint

Before reaching the question of whether a marketing claim is substantiated, Plaintiffs must first prove what claims are actually conveyed in an advertisement. Marketing claims can be express or implied. The fact finder can determine that a claim is express if, on the face of the advertisement, the marketing claim is not susceptible to more than one reasonable interpretation. *See FTC v. Alcoholism Cure Corp.*, No. 3:10-CV-00266, 2011 WL 13137951, at *25 (M.D. Fla. Sept. 16, 2011); *FTC v. Nat'l Urological Group, Inc.*, 645 F. Supp. 2d 1167, 1189 (N.D. Ga. 2008), *aff'd* 356 Fed. App'x (D.C. Cir. 2010); *In re: KIND LLC "Healthy and All Natural" Litig.*, Civ. Act. Nos. 15-MD-2645, 15-MC-2645, 2022 WL 4125065, *7 (S.D.N.Y. Sept. 9, 2022); *Hughes v. Ester C Co.*, 330 F. Supp. 3d 862, 871 (E.D.N.Y. 2018); *Stokely-Van Camp, Inc. v. Coca-Cola Co.*, 646 F. Supp. 2d 510, 525 (S.D.N.Y. 2009). However, if the marketing language is susceptible to more than one reasonable interpretation, the claim is implied. *See Ester C Co.*, 330 F. Supp. 3d at 871-72; *Stokely-Van Camp, Inc.*, 646 F. Supp. 2d at 525-26. Here, certain of the Challenged

Claims are susceptible to multiple interpretations depending on the sophistication of the person reviewing them.

The parties dispute the level of evidence needed to prove an implied marketing claim. Defendants submit that extrinsic evidence, such as a consumer survey and testimony from an expert in the field of consumer perception, is required to establish whether a significant portion of consumers would interpret the advertisement as making the alleged implied claim that Plaintiffs believe they made. *See Alcoholism Cure Corp.*, 2011 WL 13137951, at *25 ("[I]f an advertisement implies a claim, the court need not conclude that the advertisement makes such a representation without evidence of consumer perception"); *Nat'l Urological Grp., Inc.*, 645 F. Supp. 2d at 1189 ("In this case, the FTC has not presented any evidence of what claims consumers perceived the advertisements to make; accordingly, any claims that the FTC contends that the advertisements make must be clear and conspicuous from the face of the advertisements."). Plaintiffs do not believe that any extrinsic evidence is required. (Dkt. 255 at 36; Dkt. 318 at 16-17.)

This distinction is a threshold issue and is critical to the conduct of the trial because Plaintiffs have not produced any extrinsic evidence of how any consumer might perceive the Challenged Claims or any of the challenged advertisements. Thus, if Defendants are correct that extrinsic evidence is required, then Plaintiffs' claims should be limited to advertisements that the Court determines expressly make the Challenged Claims identified in the Complaint

Despite their failure to proffer extrinsic evidence, it appears that Plaintiffs intend to extend their claims more broadly than the specific marketing language identified in their Complaint. Indeed, when asked in discovery to "[i]dentify each Product Descriptor, marketing statement, advertising statement, and/or claim You contend Defendants made relating to Prevagen that You are challenging in this Action as false, misleading, and/or [] unsubstantiated," Plaintiffs responded

that they were challenging "any representation made by Defendants, whether directly *or indirectly*, expressly *or by implication*, that the Prevagen Products improve memory, improve memory within 90 days, reduce memory problems associated with aging, or provide any other cognitive benefits, including but not limited to, healthy brain function, a sharper mind, or clearer thinking." (Graham Declaration Ex. A, No. 5[3] (emphasis added).) But Plaintiffs refused to identify the specific marketing language that they contend "indirectly" or "by implication" conveys the Challenged Claims.

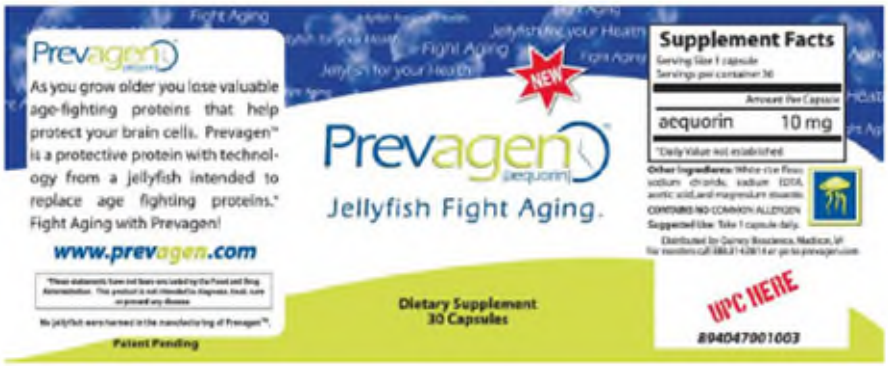
Recognizing the importance of this information, the Court subsequently compelled Plaintiffs to produce a fair and representative sample of the marketing material they intended to present at trial. (Dkt. 148.) Plaintiffs' "sample" did not comply with the spirit of the Court's Order, as it included over 1,600 pages of marketing material. Plaintiffs later added approximately 450 additional pages of marketing material to their "sample," and added even more material to their exhibit list. (Dkt. 222 ¶ 45; Dkt. 222-41; Dkt. 299-3.) Defendants asked Plaintiffs to update their sample, but they have refused to do so. (Exs. B, C.)

Thus, Defendants have been forced to conduct discovery, hire experts, move for summary judgment, and prepare their pretrial submission without *any* certainty regarding: (1) whether any marketing claims other than the Challenged Claims identified in the Complaint are being challenged in this Action; (2) whether Plaintiffs intend to argue that Prevagen advertisements without the exact language identified in the Complaint convey any implied marketing claims; (3) if so, which Prevagen advertisements convey implied marketing claims; or (4) what those implied marketing claims are. Defendants hereby provide a few examples of how Plaintiffs' ambiguity during discovery should impact the presentation of their case at trial.

[3] References to Exhibits A—E refer to the exhibits to the Declaration of Glenn T. Graham filed herewith.

1. The Advertisements Do Not Expressly Make the Challenged Claims

Plaintiffs have included "[a]ll labeling," in their "sample," which includes the following Prevagen label from 2007:



This label does not expressly make any of the Challenged Claims – it does not say that Prevagen "improves memory," "improves memory within 90 days," "reduces memory problems associated with aging," provides other cognitive benefits, including but not limited to, healthy brain function, a sharper mind, and clearer thinking," or is "clinically shown" to do anything. But this label is included on Plaintiffs' "sample," and so it appears that Plaintiffs contend that this label *implies* one or more of the Challenged Claims. (Dkt. 222-41, No. 3.) Plaintiffs have failed to present any evidence that consumers interpreted this label as conveying one of the Challenged Claims, and Defendants submit that Plaintiffs should be precluded from challenging this label at trial. However, to the extent Plaintiffs are permitted to present this label, Defendants are entitled to know *before trial* whether Plaintiffs contend that this label (and other labels or advertisements that do not expressly recite the Challenged Claims) conveys an implied marketing claim and, if so, what that implied claim is.

2. "Clinically Shown" Claims

Plaintiffs are also challenging claims that Prevagen is "clinically shown" to provide memory and cognitive benefits. While this language does appear in advertisements referenced in

the Complaint, Defendants submit that it is reasonably susceptible to more than one interpretation (all of which are fully substantiated, as set forth in Quincy's summary judgment motion). Defendants contend that "clinically shown" means that the claim is supported by a clinical trial, such as the Madison Memory Study. That contention is based in fact. Plaintiffs, on the other hand, appear to contend that "clinically shown" means a drug-level (or higher) RCT that complies with a number of stringent criteria that are not articulated in the FTC Guidance and that Plaintiffs are demanding in this case. Thus, to the extent Plaintiffs contend that "clinically shown" means something other than its plain language and the ordinary meaning understood by a reasonable person, they were required—but failed—to present evidence of how consumers perceive the advertisements supporting their interpretation. This evidentiary burden is especially important in light of Plaintiffs' assertions in this litigation that the terms "clinical" and "RCT" are vague and ambiguous. (Dkt. 281 ¶¶ 89, 118.) These admissions support Defendants' position that any "clinically shown" claims are reasonably susceptible to more than one interpretation.

3. The *Collins* Qualifiers

Plaintiffs also appear to be challenging advertisements disseminated after the *Collins* Settlement that contain one of the two court-approved Qualifiers. (Dkt. 254 at 33-36.) More specifically, they argue based on their own say-so that the Qualifiers are "insufficiently prominent" and "incapable of altering the deceptive net impression of Defendants' ads." (*Id.*) But, again, Plaintiffs have failed to proffer any evidence regarding what "net impression" is conveyed by Defendants' advertising, or regarding the impact and prominence of the Qualifiers. Absent such evidence, they should not be permitted to present these arguments at trial.

B. The Parties Appear to Dispute Whether the Challenged Claims are Structure-Function Claims or Disease Claims

Once it has been established what marketing claims are being challenged and what those claims convey, a determination must also be made whether the claim is a structure-function claim or a disease claim. (Dkt. 222-6 at 3-4, 26, n.2, n.3.) The distinction is critical, as it dictates what level of substantiation is required.

Structure-function claims "refer to representations about a dietary supplement's effect on the structure or function of the body for maintenance of good health and nutrition." (*Id.* at 26, n.2.) The FTC Guidance states that structure-function claims are not subject to FDA pre-authorization, and can be made if they include the required DSHEA disclaimer that the product is not intended to "diagnose, treat, cure or prevent any disease" and are truthful and not misleading (*i.e.*, are supported by "competent and reliable scientific evidence" as set forth in the FTC Guidance). (Dkt. 222-6 at n.3.) In contrast, a disease claim is a claim that suggests treatment, diagnosis, cure, or prevention of a disease. Disease claims require FDA approval of a new drug application supported by RCTs. Defendants make no such claims and Plaintiffs cannot credibly argue otherwise.

The Parties dispute the significance of these regulatory distinctions and how the Challenged Claims should be characterized. Defendants' position is that all of the Challenged Claims identified in the Complaint are permissible structure-function claims and therefore are substantiated by "competent and reliable scientific evidence" as defined in the FTC Guidance. Plaintiffs, on the other hand, argue—without any legal support—that the "structure-function claims" and "disease claim" regulatory categories should be collapsed and that, as a result, all claims relating to a person's "health" must be supported by a drug-level RCT that would be sufficient to obtain FDA approval for a new drug application (which, in any event, Defendants

possess). (Dkt. 222-31 at 15-16, No. 37.) Here, all of the Challenged Claims (*i.e.,* "improves memory," "improves memory within 90 days," "reduces memory problems associated with aging," and "provides other cognitive benefits, including but not limited to, healthy brain function, a sharper mind, and clearer thinking") are permissible structure-function claims. There are no references to any disease. Indeed, the FDA has issued guidance with examples of permissible structure-function claims and one such example—addressing "mild memory loss associated with aging"—is quite similar to the Challenged Claim in this Action. (Dkt. 222-10 at 6-7.) Moreover, it is undisputed that every package of Prevagen sold since 2007 states that the product "is not intended to diagnose, treat, cure, or prevent any disease." (Dkt. 224 ¶ 7.)

To the extent Plaintiffs argue that Defendants made *implied* disease claims that are not apparent from the face of the advertisements, they must provide extrinsic evidence that consumers interpreted the advertising as conveying a disease claim. *See Nat'l Urological Grp., Inc.*, 645 F. Supp. 2d at 1189 ("[T]he court will not presume, without extrinsic evidence, that a recipient of these advertisements would infer that [the product] is clinically proven to treat obesity from the clinical weight loss claims.") There is no such evidence in the record and, to the extent Plaintiffs attempt to further such a theory at trial, they will not be able to meet their burden of proof.

C. The Parties Disagree About How the "Competent and Reliable Scientific Evidence" Standard Should be Applied to Quincy's Proffered Substantiation

The relevant substantiation standard for Plaintiffs' claims is set forth in the FTC Guidance, which explains that dietary supplement marketing claims must be substantiated by "competent and reliable scientific evidence," defined as "tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area." (Dkt. 222-6 at 9.) The FTC Guidance makes clear that this standard is "sufficiently flexible to ensure that consumers have access to information

about emerging areas of science" (*id.* at 8), and contains, among others, the following relevant provisions:

- There is no fixed formula for the number or type of studies required or for more specific parameters like sample size and study duration. (*Id.* at 8-9.)
- The FTC will consider all forms of competent and reliable scientific research when evaluating substantiation, including, but not limited to, animal studies, *in vitro* studies, epidemiological evidence, and human studies. (*Id.* at 10.)
- There is no requirement that a claim regarding a dietary supplement be supported by any specific number of studies. (*Id.* at 10.)
- There is no set protocol for how to conduct research that will be acceptable under the FTC substantiation doctrine. (*Id.* at 12.)
- Studies cannot be evaluated in isolation. (*Id.* at 14.)
- Randomized human clinical trials are not required. (*Id.* at 9-18); *Bayer Corp.*, 2015 WL 5822595, at *3-4.

Courts around the country have recognized and therefore held that the FTC Guidance sets forth the governing competent and reliable scientific evidence standard for substantiation of dietary supplement structure/function claims such as those at issue in this Action. *See, e.g., Bayer Corp.*, 2015 WL 5822595, at *3-4; *FTC v. Garden of Life, Inc.*, 516 Fed. App'x 852, 854-58 (11th Cir. 2013); *Basic Rsch. LLC v. FTC*, No. 2:09-CV-0779, 2014 WL 12596497, at *9-11 (D. Utah Nov. 25, 2014); *see also Nat'l Urological Grp., Inc.*, 645 F. Supp. 2d at 1186-1187 (noting that the "[c]ompetent and reliable scientific evidence" standard has been defined in "guidelines promulgated by the FTC" and discussing the FTC Guidance.) And yet, Plaintiffs have continued to avoid application of the FTC Guidance in this case. As such, the following disputed areas of law with respect to the FTC Guidance may arise at trial.

1. Animal Studies Should Be Considered

Defendants have amassed significant evidence from animal studies that show apoaequorin has a cognitive benefit. This includes studies using rodents and conducted at the University of

Wisconsin-Milwaukee, and also studies conducted through a sponsored research agreement using canine models. Both reported that apoaequorin provides a cognitive benefit and results from these studies were published in peer-reviewed journals. (Dkt. 223 ¶¶ 13-19; Dkts. 223-1—223-15.) Defendants have also cited animal studies suggesting that vitamin D is linked to alterations in learning and memory and reduced attentional processing. (Dkt. 222-18 ¶ 60.) Despite the FTC Guidance's pronouncement that animal studies will be considered as competent and reliable scientific evidence (Dkt. 222-6 at 10; *see also Bayer Corp.*, 2015 WL 5822595, at *3), Plaintiffs and their experts have either wholly ignored these animal studies or baldly declared them to be irrelevant.

2. Open Label Human Clinical Research and *In Vitro Studies* Should Be Considered

Defendants also have substantial open label human clinical research to support the Challenged Claims. Quincy conducted the Open Label Trial, wherein 55 adult participants received 10 mg of apoaequorin per day over 90 days and responded to a battery of questions from the SF-36 Survey, a standardized measure of health status, and ERA-38 Survey, the purpose of which is to measure changes in expectations regarding aging among older adults. (Dkt. 223 ¶ 20; Dkt. 223-16.) The Open Label Trial reported a statistically significant benefit on questions related to cognitive function, fatigue, sleep, and general health for participants. (Dkt. 223-16.)

In addition, Sunsho Pharmaceuticals, Ltd. ("Sunsho"), conducted a clinical trial testing the efficacy of Prevagen on cognitive functioning and quality of sleep. The Sunsho trial noted that, after 30 days of intake of Prevagen, there was "a confirmed rise in the score which showed a statistically significant difference from the score before intake" and that "the effect of 'Prevagen' can be considered to be favorable from the viewpoint of its use as a brain supplement." (Dkt. 223 ¶ 32; Dkt. 223-21.)

Defendants have also cited voluminous human clinical research, including cross-sectional studies, prospective studies, case-control studies and meta-analyses, showing beneficial associations between higher vitamin D levels or higher vitamin D intake and cognitive function. (Dkt. 222-18 ¶¶ 63-64, 66-69.) In addition, *in vitro* studies have shown that vitamin D influences neuronal development, neuroplasticity, neuronal growth and neuroprotection, and demonstrate beneficial associations between vitamin D and brain structure. (*Id.* ¶¶ 60-61.)

Plaintiffs have improperly ignored or discounted this evidence, disregarding the FTC Guidance's pronouncement that "all forms of scientific evidence will be considered." (Dkt. 222-6 at 10); *see also Bayer Corp.*, 2015 WL 5822595, at *3.

3. The FTC Guidance Does Not Require Randomized Controlled Trials, Let Alone the Heightened Drug-Level Trial Plaintiffs Seek to Impose

Federal courts have recognized that "the FTC Guidance makes clear that [the competent and reliable scientific evidence] standard *is not the drug standard. Randomized clinical trials are not required.*" *Bayer*, 2015 WL 5822595, at *3 (emphasis added) (citing FTC Guidance at 9-18 (Dkt. 222-6).) Contrary to that Guidance, Plaintiffs have taken the position in this case that a heightened drug-level randomized clinical trial is required to substantiate the Challenged Claims—and Quincy has still satisfied this completely made-up requirement.

Despite not being required to have RCT substantiation, Quincy conducted the Madison Memory Study (Dkt. 223-17), a 90-day randomized, double-blind, placebo-controlled study designed "to determine whether Prevagen with apoaequorin (10 mg) improves quantitative measures of cognitive function in community dwelling, older adults." (Dkt. 221 ¶ 96; Dkt. 223-17 at 2; Dkt. 1 ¶ 28); *Quincy Bioscience*, 272 F. Supp. 3d at 553. The Madison Memory Study demonstrated statistically significant results in the targeted study groups, which "contain individuals with either minimal or no cognitive impairment, and are the appropriate population for

a dietary supplement intended to support people with mild memory loss associated with aging." (Dkt. 221 ¶ 109.) Specifically, results showed that participants in the treatment group with AD8 scores of 0-2 showed statistically significant improvements as compared to placebo recipients on three different Cogstate tests measuring cognitive function, and outperformed the placebo group on four additional tests. (*Id.* ¶ 110.) Participants in the treatment group with AD8 scores of 0-1 also experienced statistically significant improvements as compared to placebo recipients on three Cogstate tests, and outperformed the placebo group on four additional tests. (*Id.*¶ 111.) The placebo group did not show any statistically significant improvement as compared to the treatment group on any of the Cogstate tasks in the AD8 0-1 and AD 0-2 subgroups. (*Id.*¶ 112.) The Madison Memory Study concluded that "Prevagen demonstrated the ability to improve aspects of cognitive function in older participants with either normal cognitive aging or very mild impairment, as determined by AD8 screening." (*Id.* ¶ 114, Dkt. 223-17 at 9; Dkt. 1 ¶ 29 (acknowledging "positive findings").)

Notwithstanding the Madison Memory Study's positive findings, and notwithstanding that the relevant guidance does not require Quincy to perform an RCT in the first instance, Plaintiffs have taken the position that the Madison Memory Study is inadequate for substantiation purposes because in their opinion the Madison Memory Study does not meet the requirements of a drug-level RCT. This position is contrary to the FTC Guidance and has never been articulated before this Action. Plaintiffs seek to impose this requirement on Quincy without a shred of regulatory or legal support. To the contrary, their attempt to impose a higher substantiation burden than what is set forth in the FTC Guidance has been rejected by other courts in the past, and should be rejected again. *See Garden of Life, Inc.*, 516 Fed. App'x at 854-58; *Bayer Corp.*, 2015 WL 5822595, at *3-4; *Basic Rsch, LLC*, 2014 WL 12596497, at *9-11.

D. The Parties Dispute Whether Plaintiffs are Entitled to Injunctive Relief

Plaintiffs seek to enjoin Defendants from making various marketing claims but have failed to establish they have authority to seek injunctive relief pursuant to the FTC Act, New York Executive Law § 63(12), and New York GBL §§ 349 and 350.

1. The FTC Has Not Met the Legal Standard for Injunctive Relief Under the FTC Act

a. Defendants Are Not "Violating" or "About to Violate" the FTC Act

To obtain injunctive relief under Section 13(b) of the FTC Act, the FTC is required to establish that an entity "is violating or is about to violate" the FTC Act. *See* 15 U.S.C. § 53(b); *AMG*, 141 S. Ct. at 1348; *Shire*, 917 F.3d at 160; *FTC v. Qualcomm, Inc.*, 969 F.3d 974, 1005 (9th Cir. 2020); *FTC v. Evans Prod. Co.*, 775 F.2d 1084, 1086-87 (9th Cir. 1985).

It is undisputed that none of the Challenged Claims are currently being disseminated in the manner alleged in the Complaint (and that many of them were not even being disseminated in that form when the Complaint was filed in 2017). It is also undisputed that Defendants have no intention of disseminating any of the Challenged Claims in the manner alleged in the Complaint in the future, either because the advertisements referenced in the Complaint have stopped running or because the *Collins* Qualifier has been added to the advertisement in connection with the court-approved *Collins* Settlement. (Dkt. 222-34 at 7-8; Dkt. 222-36; Dkt. 224 ¶¶ 41-45.) Because there is no evidence that Quincy is disseminating or is "about to" disseminate the advertisements in the same form challenged in the Complaint, the FTC is not entitled to injunctive relief as a matter of law. *See* 15 U.S.C. § 53(b); *AMG*, 141 S. Ct. at 1348.

b. This is Not a "Proper Case" for Permanent Injunctive Relief

The FTC is not entitled to a permanent injunction for the independent reason that it did not seek a temporary restraining order or preliminary injunction at the outset of this litigation. The

FTC's entitlement to injunctive relief is subject to two provisos in the FTC Act: first, if an administrative complaint is not filed within a period not to exceed 20 days, the temporary restraining order or preliminary injunction shall be dissolved; and second, "***in proper cases*** the Commission may seek, and after proper proof the court may issue, a permanent injunction." 15 U.S.C. § 53(b) (emphasis added). In *AMG*, the Supreme Court suggested (without holding) that, in this context, "the appearance of the words 'permanent injunction' (as a proviso) suggests that these words are directly related to a previously issued preliminary injunction." 141 S. Ct. at 1348. Here, the FTC never sought a preliminary injunction or even a temporary restraining order. The failure by the FTC to move for either a preliminary injunction or a temporary restraining order is odd because the agency conducted a full investigation into Quincy's marketing practices before filing this Action nearly six years ago, and had already received over 200,000 pages of investigative discovery in response to its civil investigative demand ***before*** it filed the Complaint in January 2017. Because the FTC failed to seek a temporary restraining order or preliminary injunction at that time (or at any time during the last half decade of litigation), it is now precluded from seeking a permanent injunction under the plain language of Section 13(b).

2. Plaintiffs Are Not Entitled to Injunctive Relief under *U.S. v. W.T. Grant Co.*

In addition to the FTC's inability to obtain injunctive relief under the FTC Act, both Plaintiffs' injunctive relief claims fail under *United States v. W. T. Grant Co.*, which requires a party seeking an injunction to show "that there exists some cognizable danger of recurrent violation, something more than the mere possibility" that the conduct complained of could be repeated. 345 U.S. 629, 633 (1953); *see also FTC v. AbbVie, Inc.*, 976 F.3d 327, 381 (3d Cir. 2020), *cert. denied*, 141 S. Ct. 2838 (2021). Numerous courts in this Circuit and elsewhere have held government agencies like the FTC and NYAG to this standard. *See, e.g., AbbVie, Inc.*, 976

F.3d at 380; *Borg-Warner Corp. v. FTC*, 746 F.2d 108, 110 (2d Cir. 1984); *SCM Corp. v. F.T.C.*, 565 F.2d 807, 812-13 (2d Cir. 1977); *FTC v. Shkreli*, 581 F. Supp. 3d 579, 638-40 (S.D.N.Y. 2022). Plaintiffs cannot satisfy the *Grant* standard for the same reason that the FTC cannot satisfy Section 13(b)—Quincy is no longer disseminating the Challenged Claims in the form challenged in the Complaint, and there is no "cognizable danger" of future dissemination given that Quincy agreed to stop disseminating the claims impacted by the *Collins* Settlement and Final Judgment.

E. The Parties Dispute Whether the NYAG's Claims are Preempted

The NYAG's claims are preempted by the Food, Drug, and Cosmetic Act ("FDCA"), the governing authority for dietary supplements such as Prevagen. The FDCA provides that "no State or political subdivision of a State may directly or indirectly establish" any labeling requirement "that is not identical to the requirement[s]" imposed by the FDCA. 21 U.S.C. § 343-1(a)(5). State laws governing labeling requirements must be coextensive with similar requirements imposed by the FDCA and DSHEA (and any resulting guidance). The NYAG, in turn, cannot impose standards more stringent than the FDCA and DSHEA. *See In re PepsiCo., Inc., Bottled Water Mktg. & Sales Pracs. Litig.,* 588 F. Supp. 2d 527, 537 (S.D.N.Y. 2008); *Bimont v. Unilever U.S., Inc.*, No. 14-CV-07749, 2015 WL 5256988, at *8-9 (S.D.N.Y. Sept. 9, 2015); *Bowling v. Johnson & Johnson*, 65 F. Supp. 3d 371, 375-77 (S.D.N.Y. 2014); *see also Greenberg v. Target Corp.,* 402 F. Supp. 3d 836, 839-42 (N.D. Cal. 2019), *aff'd*, 985 F.3d 650 (9th Cir. 2021); *Mills v. Giant of Md., LLC*, 441 F. Supp. 2d 104, 106-09 (D.D.C. 2006), *aff'd*, 508 F.3d 11 (D.C. Cir. 2007).

In fact, the GBL itself contains a safe harbor provision which provides a "complete defense" if the complained-of practices are permitted by federal law. *See* GBL §§ 349(d), 350; *Manchanda v. Educ. Credit Mgmt. Corp*., No. 1:19-CV-05121, 2022 WL 137885, at *2 (S.D.N.Y. Jan. 14, 2022); *Izquierdo v. Mondelez Int'l, Inc.*, No. 1:16-CV-04697, 2016 WL 6459832, at *3-4 (S.D.N.Y. Oct. 26, 2016); *see also Colella v. Atkins Nutritionals, Inc*., 348 F. Supp. 3d 120, 134-

37 (E.D.N.Y. 2018); *Am. Home Prod. Corp. v. Johnson & Johnson*, 672 F. Supp. 135, 144 (S.D.N.Y. 1987). As a matter of law, the NYAG cannot impose a higher standard on Prevagen's marketing claims than what is already permitted by federal law and its attempt to do so should be preempted.

F. The Parties Dispute Whether the NYAG is Entitled to Recover Restitution on Behalf of New York Consumers Who Purchased Prevagen Prior to the *Collins* Settlement

It is well established that government agencies like the NYAG cannot seek restitution on behalf of individual consumers whose claims have been released by a class settlement.[4] *See In re Baldwin-United Corp*., 770 F.2d 328, 339 (2d Cir. 1985); *California v. IntelliGender, LLC*, 771 F.3d 1169, 1172 (9th Cir. 2014). Here, the *Collins* Settlement, which has been reduced to a final judgment entered by a district court, specifically releases Defendants "from all claims, demands, actions, and causes of action of any kind or nature whatsoever" that they "ever had, now have, may have, or hereafter can, shall or may ever have against the [Defendants] in any court, tribunal, arbitration panel, commission, agency, or before any governmental and/or administrative body, or any other adjudicatory body, on the basis of, arising from, or relating to the claims alleged in the Action." (Dkt. 222-34 at 6, 12; Dkt. 222-36.) Thus, as a matter of law, the NYAG is not entitled to recover restitution on behalf of New York residents who purchased Prevagen prior to the *Collins* Settlement. *See Applied Card Sys.,* 11 N.Y.3d at 109 (holding that "res judicata effect should be granted to a prior nationwide class action settlement, thereby precluding the Attorney General from recovering certain restitution"); *Silvar v. Comm'r of Lab. of N.Y.*, 175 A.D.3d 95, 104 (1st Dep't 2019) (holding that *res judicata* barred the Commissioner of Labor for the State of New York from

[4] As discussed in Quincy's summary judgment briefing, the NYAG appears to have conceded this point. (*See* Dkt. 278 at 41-42.)

pursuing wage claims that had been released as part of a prior class action settlement); *FTC v. AMREP Corp*., 705 F. Supp. 119, 125 (S.D.N.Y. 1988) (dismissing the FTC's claim for restitution on behalf of consumers that participated in prior class action settlement).

G. Quincy Disputes the NYAG's Proposed Methods of Calculating Civil Penalties

The NYAG has stated that "it will calculate its claim for penalties of $5000 for each violation of GBL Article 22-A." (Dkt. 163-5, Supp. No. 2.) The NYAG has also stated that it anticipates defining each "violation in a cumulative manner: "each deception of New York consumers in terms of each airing of a radio or television ad in the State of New York; each dissemination of a book or pamphlet advertising the Prevagen Products in the State of New York; each day on which the Prevagen Products, including the deceptive packaging claims, were available for purchase in New York retail outlets; ***and*** each day on which Quincy Bioscience advertised the Prevagen Products on a website accessible to New York consumers." (*Id.* (emphasis added).) Putting aside the fact that the NYAG has not uncovered evidence in discovery to support any of these proffered calculation methodologies (*see* Section J, *infra*), Quincy submits that this cumulative method of calculating the number of alleged violations would result in excessive penalties in violation of the Excessive Fines Clause of the Eighth Amendment. *See Timbs v. Indiana*, 139 S. Ct. 682 (2019).[5]

VI. EVIDENTIARY ISSUES LIKELY TO ARISE AT TRIAL

In addition to Defendants' pending *Daubert* motion, which sought to exclude testimony from each of Plaintiffs' four experts (Dkts. 306—308, 320—321), Defendants summarize below

[5] Alternatively, the NYAG has suggested that "'[v]iolations' could also be defined as each sale of a Prevagen Product, such that [Quincy] would owe penalties of up to $5000 for each sale." (Dkt. 163-5, Supp. No. 2.) Quincy contends that this, too, would result in an excessive and unconstitutional penalty.

the key evidentiary issues that Defendants anticipate arising at or before trial. Defendants will submit full briefing on these issues at the Court's request.

A. Plaintiffs Should Be Required to Provide an Updated Sample of the Advertisements They Intend to Present at Trial to Avoid Undue Surprise and Prejudice to Defendants

Despite numerous requests throughout this litigation, Plaintiffs have yet to identify exactly ***which*** marketing claims and advertisements they intend to challenge at trial other than those specifically identified in the Complaint. They should be required to do well in advance of trial so to avoid undue surprise and prejudice to Defendants or, in the alternative, they should be limited to the marketing claims and advertisements specifically set forth in their Complaint.

As discussed above, the Court previously ordered Plaintiffs to produce a fair and representative sample of the advertisements and marketing material they intend to present at trial. (Dkt. 148.) Their "sample," as amended, includes over 2,000 pages of marketing material. (Dkt. 222-41.) Compounding the matter further, Plaintiffs' exhibit list includes *additional* pieces of marketing that were not previously disclosed in Plaintiffs' "sample." (Dkt. 299-3.) On August 30, 2022, Defendants asked Plaintiffs to update their sample, as provided for in the Court's December 3 Order, but Plaintiffs refused to do so. (Exs. B, C.)

The parties are now on the eve of trial, and Defendants still do not know which marketing materials, or even all of the marketing *claims*, Plaintiffs intend to challenge at trial. Rather, it appears that Plaintiffs prefer to spring this information on Defendants during the trial itself. But this is not how litigation in federal court works and, absent the requested information, Defendants will not be able to adequately prepare their witnesses for trial. *See Am. Stock Exch., LLC v. Mopex, Inc.*, 215 F.R.D. 87, 93 (S.D.N.Y. 2002) (stating that the "purpose" of pretrial discovery rules "is to avoid surprise or trial by ambush.") (citations omitted). Plaintiffs should be compelled to identify exactly which marketing claims they intend to challenge at trial, and to provide a fair and

representative sample of the marketing material that they actually intend to present at trial, which should consist of 20 or fewer pieces of evidence. In the alternative, Plaintiffs should be limited to the advertisements and marketing claims identified in their Complaint

B. Advertisements and Labels for Prevagen That Are No Longer Being Disseminated Should Be Excluded as Irrelevant and Prejudicial

Plaintiffs appear to be challenging voluminous Prevagen advertising and labeling that is no longer being disseminated.[6] As discussed above, to qualify for injunctive relief, the FTC must establish that Defendants are "about to" re-disseminate these terminated advertisements, and both Plaintiffs are required to "some cognizable danger" of future dissemination. (Section D, *supra*.) The undisputed evidence, however, demonstrates that Quincy stopped disseminating the advertisements in question and has no intention of disseminating them in the future as reflected in the court-approved *Collins* Settlement Agreement. (Section D, *supra*.) Thus, because Defendants are not "about to violate" the FTC Act with respect to these advertisements, and there is no "cognizable danger of recurrent violation," these advertisements are irrelevant to the claims at issue and should be excluded under F.R.E. 401. *See U.S. v. Aiyer*, 33 F.4th 97, 123 (2d Cir. 2022) (finding "evidence is relevant if: (a) it has any tendency to make a fact more or less probable than it would be without the evidence; and (b) the fact is of consequence in determining the action" and that "irrelevant evidence is *not* admissible." (cleaned up) (emphasis in original).

These advertisements are also irrelevant to the NYAG's claim for restitution, which is limited to New York consumers who purchased Prevagen *after* the July 2020 settlement in *Collins*. (Dkt. 227 at 45-48; Dkt. 255 at 51-52.) Since the advertisements did not run after July 2020 in the

[6] *See e.g.,* PX-20, 23, 32, 34, 52—65, 66—86, 102—103, 111—112, 116, 118—123, 143, 151—152, 154—157, 210, 214—271, 221, 225, 227—234, 408—411, 412—418, 420, 421—428, 434—435, 439—445, 454—456, 464—465, 469—472, 473—484, 486—491, 493—495, 543—544, 546—550, 553.

form challenged, they are not relevant to the NYAG's restitution claim and should be excluded under F.R.E. 401.[7]

Finally, since these advertisements cannot give rise to liability, their admission into evidence would only serve to confuse the jury and unduly prejudice Defendants insofar as they would put advertising language before the jury that it does not need to consider and that may impact its views on other advertising that remains at issue. These advertisements should be excluded under F.R.E. 403. *See Hart v. RCI Hospitality Holdings, Inc.*, 90 F. Supp. 3d 250, 257 (S.D.N.Y. 2015) ("Evidence is considered prejudicial if it 'involves some adverse effect . . . beyond tending to prove the fact or issue that justified its admission into evidence.'") (citations omitted); *Gerber v. Comput. Assocs. Int'l, Inc.*, 303 F.3d 126, 137 (2d Cir. 2002) ("In applying Rule 403, the trial judge has broad discretion to weigh the probative value of the evidence against the negative factors.") (citation omitted).

C. Advertisements Disseminated on Third Party Websites Should Be Excluded as Unauthenticated and Prejudicial

Documents must be authenticated before they can be admitted into evidence. F.R.E. 901. Most often, authentication is accomplished through the "testimony of a witness with knowledge that a matter is what it is claimed to be." *U.S. v. Gagliardi*, 506 F.3d 140, 151 (2d Cir. 2007). Plaintiffs' exhibit list contains approximately 100 exhibits the FTC produced in discovery that purport to be print, radio and video advertisements that the FTC captured from websites operated by Defendants and/or by various third parties over the last eight years. (Dkt. 299-3.)[8] For many of these exhibits, Plaintiffs have failed to provide any authenticating testimony explaining the

[7] Following investigation, due to an oversight and production error, certain limited videos aired without the Qualifier. Upon being notified of the oversight, the issue was corrected. (Dkt. 280 ¶¶ 5—7.)

[8] *See, e.g.,* PX-436—439, 441—442, 454—460, 462—491, 493—495, 497—509, 514—534, 543—553, 555—558, 560—562, 564.

source of the material, who created the material, who printed the exhibits or when they were printed, nor have they identified any witnesses who may be able to present such testimony. In fact, Plaintiffs have "stipulate[d] that they do not intend to call any FTC or NYAG employees identified in the amended disclosures as trial witnesses." (Ex. D.) These exhibits should be excluded from trial under F.R.E. 901. *See U.S. v. Vayner*, 769 F.3d 125, 132–33 (2d Cir. 2014) (finding the lower court abused its discretion when it admitted unauthenticated evidence of a defendant's online social media profile, because "the mere fact that a page with [the defendant's] name and photograph happened to exist on the Internet . . . does not permit a reasonable conclusion that this page was created by the defendant or on his behalf"); *Boykin v. W. Express, Inc.*, No. 7:12-CV-07428, 2016 WL 8710481, at *5 (S.D.N.Y. Feb. 5, 2016) (finding additional evidence necessary to authenticate a video, because plaintiff's own admission that she "is the individual depicted in the video . . . alone does not confirm the genuineness or authenticity of what . . . was truly and accurately before the camera.").

Plaintiffs have also included one exhibit[9] that appears to be a printout from a website as it appeared in 2013 (nearly ten years ago) obtained through a service called the "Wayback Machine," which purports to allow a user to obtain an archived webpage as it appeared at a particular moment in time. Courts in this Circuit have excluded documents obtained through the Wayback Machine in the absence of authenticating evidence. *See, e.g., Novak v. Tucows, Inc.*, No. 2:06-CV-01909, 2007 WL 922306, at *5 (E.D.N.Y. Mar. 26, 2007), *aff'd* 330 Fed. App'x 204 (2d Cir. 2009). Because Plaintiffs cannot provide any authenticating testimony for this document, it should be excluded.

[9] *See* PX-484.

Not only do these documents lack evidence of authenticity, their admission could severely prejudice Defendants to the extent that these advertisements were disseminated (and potentially edited) by third parties without Defendants' knowledge or consent. Defendants would be further prejudiced to the extent they lacked control over the third parties' dissemination of the advertisements, particularly if the third party continued to run the advertisement after Quincy itself ceased its dissemination.[10] *Hart*, 90 F. Supp. 3d at 257. Accordingly, these advertisements should be excluded under F.R.E. 901 and F.R.E. 403.

D. All Documents and Testimony Relating to the FDA's 2012 Warning Letter Should Be Excluded

On October 16, 2012, the FDA issued a warning letter to Mark Underwood as president of Quincy Bioscience Manufacturing, Inc. concerning Prevagen. (Dkt. 299 ¶ 39; PX-405.)

The Warning Letter is irrelevant to Plaintiffs' claims, constitutes hearsay and is prejudicial for at least three reasons. First, the Warning Letter contains unproven allegations, rather than the "facts" that Plaintiffs are required to submit to prove their claims. Indeed, the FDA never filed an enforcement action regarding the allegations set forth in the Warning Letter. In fact, the FDA ultimately closed the warning letter without taking any action as set forth below. Second, it relates to alleged marketing that occurred well-before the filing of the Complaint. Third, Quincy responded to the Warning Letter and the FDA issued a Close Out Letter on June 13, 2018, acknowledging that any issues raised in the Warning Letter were resolved. Plaintiffs admit they were not even aware of this fact until years into this litigation. (Dkt. 222-31, No. 100; Dkt. 279-1.) Thus, the Warning Letter has no relevance to Plaintiffs' claims and would only serve to prejudice the jury against Defendants. *See Smith v. I-Flow Corp.*, No. 1:09–CV-03908, 2011 WL

[10] *See, e.g.,* PX-473—484, 544, 546—550 , 553.

12627557, at *2 (N.D. Ill. June 15, 2011) (excluding FDA warning letter "as irrelevant and under Federal Rule of Evidence 403 due to the potential for unfair prejudice that far outweighs any limited probative value the letter might have regarding the issues the jury will be called upon to decide"); *Heath v. C.R. Bard Inc.*, No. 3:19-CV-00803, 2021 WL 4481533, at *1-2 (M.D. Tenn. Sept. 30, 2021) (excluding FDA warning letter that did not relate to the issues being litigated as irrelevant and prejudicial).

Indeed, Plaintiffs' attempt to rely on the Warning Letter is *doubly* prejudicial, as it appears that Plaintiffs intend to present the Warning Letter at trial but shield Quincy's response and the FDA's Close Out Letter from the Court and/or the jury's consideration. In other words, it seems that Plaintiffs believe that FDA enforcement activities are relevant when they support *Plaintiffs'* position in this litigation, but that Defendants should not be given an opportunity to present evidence that the FDA abandoned its allegations when provided with Quincy's response to the issues raised in the Warning Letter.

Defendants respectfully request that the FDA's Warning Letter and any testimony relating thereto be excluded from trial in its entirety to avoid undue prejudice to Defendants. Alternatively, if the Court finds that the Warning Letter is admissible and an appropriate subject of inquiry at trial, Defendants request that their response to the Warning Letter and the FDA's Close Out Letter and related testimony also be allowed into evidence.[11]

E. Documents and Testimony Relating to Trials that Quincy Does Not Rely on to Substantiate the Challenged Claims Should Be Excluded

As discussed in detail above, Quincy has conducted over a decade of research focused on the target market for Prevagen, which is healthy older adults with mild memory concerns due to

[11] The Warning Letter is also hearsay and should be excluded from evidence pursuant to Rules 801 and 802 of the Federal Rules of Evidence.

aging. (Dkt. 223 ¶¶ 13-32.) However, Quincy has also conducted exploratory research to see if apoaequorin provides any benefits to other populations, such as individuals with multiple sclerosis (the "MS Hope Trial"), individuals with fibromyalgia and/or chronic fatigue syndrome (the "Prevagen Fibromyalgia/Chronic Fatigue Study"), and college students (the "Memory Improvement Trial"). (*Id.* ¶¶ 18-19.) Documents relating to these trials are not relevant to any of Plaintiffs' claims—their results have not been published, and Defendants do not rely on them to substantiate the Challenged Claims (although both completed trials demonstrated that apoaequorin had a beneficial effect on cognition). They should be excluded as irrelevant under F.R.E. 401.[12] *See Aiyer*, 33 F.4th at 123.

Such evidence would also prejudice Defendants to the extent it would suggest that Prevagen was marketed to cure or treat a disease, which is not the case. It is undisputed that every package and label of Prevagen sold since 2007 described Prevagen as a "dietary supplement" and contained the explicit disclaimer that the product "is not intended to diagnose, treat, cure, or prevent any disease." (Dkt. 257 ¶¶ 13-14.)[13] Accordingly, all documents relating to the MS Hope Trial, Prevagen Fibromyalgia/Chronic Fatigue Study, and Memory Improvement Trial should be excluded under F.R.E. 403. *See Smith,* 2011 WL 12627557, at *2; *Heath*, 2021 WL 4481533, at *1-2.

F. Documents and Testimony Relating to James Lugo Should be Excluded as Irrelevant, Prejudicial, and Hearsay

Plaintiffs should be precluded from offering any documentary or testimonial evidence from or relating to purported opinions of an individual named James Lugo (PX-206, PX-150), and any

[12] *See* PX-98—99, 105, 124—126, 130; PX-274—275, 401, 406; PX-218, 276—277, 282.

[13] Plaintiffs purported to contest these facts on summary judgment as "irrelevant and immaterial," but their response to Quincy's 56.1 Statement failed to provide any evidence to dispute the cited testimony. (Dkt. 257 ¶¶ 13-14.)

other undisclosed, unauthenticated, or supposed scientific opinions (PX-211, PX-212), as such evidence is both inadmissible hearsay and would prejudice Defendants.

Plaintiffs listed two documents on their exhibit list that purport to be authored by or contain comments from James Lugo. (PX-206 and PX-150.) The first (PX-206) is an email from Mark Underwood to Michael Beaman which purports to contain Lugo's email signature at the bottom of the document. The second (PX-150) is an email from Mr. Underwood to Mr. Beaman with an attachment that, according to Plaintiffs' counsel, contained metadata showing that Lugo was the author of the attachment. (Ex. E, Underwood Tr. at 142:14—144:5.) Despite being presented with both of these documents at his deposition, Mr. Underwood testified that he was not familiar with Lugo, that he did not recall receiving any email communications from Lugo, that he did not recall corresponding with Lugo, that he did not know why Lugo was reviewing Quincy's science, and that Quincy did not retain Lugo as an expert. (Ex. E, Underwood Tr. at 118:9—122:7, 134:23—135:18, 144:6-11.) Defendants also stated in an interrogatory response that "they do not have a 'relationship' with James Lugo, nor are they aware of any communications between Defendants and James Lugo." (Dkt. 240-3, No. 22.) To the extent that the comments in these two documents actually reflect the writings of Lugo—a fact which has not been established—the documents should be excluded from evidence because they lack foundation, have not been authenticated, and are hearsay. *See Elghourab v. Vista JFK, LLC*, No. 1:17-CV-00911, 2018 WL 6182491, at *2 (E.D.N.Y. Nov. 27, 2018) (finding "documentary evidence such as emails" must be authenticated and "must also be not hearsay or fall under a hearsay exception" to be admissible); *see also CA, Inc. v. Simple.com, Inc.*, 780 F. Supp. 2d 196, 227 (E.D.N.Y. 2009) ("An email offered for the truth of its contents is hearsay and must satisfy an applicable hearsay exception."); *see also Vayner*, 769 F.3d at 132–33.

Admission of these documents, or testimony concerning these documents, would also unduly prejudice Defendants to the extent Lugo has not been disclosed as an expert and to the extent Plaintiffs attempt to characterize him as an "expert," as they did during Mr. Underwood's deposition. (Ex. E, Underwood Tr. 127:11—128:2.) No party has retained Lugo as an expert, his qualifications (if any) have not been put before this Court, and Defendants have not had the opportunity to test his qualifications, methodology or his opinions. These documents, as well as any testimony regarding Lugo's purported "opinions" should be excluded.[14]

G. Plaintiffs and Their Experts Should Be Precluded From Making Any References to "Post Hoc" Subgroup Analyses at the Trial

Plaintiffs alleged in their Complaint that Defendants reported statistically significant results from the Madison Memory Study were the result of "post hoc" subgroup analyses of participants who scored between 0 and 2 on the AD8 scale, which they define as analyses that were conducted after Quincy's researchers reviewed and analyzed the study data. (Dkt. 1 ¶ 29.) Despite years of discovery, Plaintiffs failed to uncover any evidence to support this allegation, and the undisputed evidence demonstrates that it is flat wrong—Quincy decided to analyze the AD8 0-1 and AD8 0-2 subgroup from the outset of the study, well-*before* any researchers reviewed or analyzed the data. This evidence was discussed extensively in Quincy's *Daubert* motion. (Dkt. 307 at 16-18; Dkt. 320 at 10-16.) Plaintiffs' experts also admitted that they had no idea when the subgroup analyses in question were actually conducted, so their conclusions that the analyses were "post hoc" was unsupported by, and contrary to, the evidence. (*Id.*)

[14] Plaintiffs should not be permitted to call Lugo to testify at trial because he has not been identified as a potential witness in any party's initial disclosures. Quincy has not had an opportunity to depose him and Plaintiffs confirmed they do not intend to call any witnesses at trial other than their four disclosed experts. *See N.Y. v. United Parcel Service, Inc.*, 15-CV-1136, 2016 WL 10672104, at *3 (S.D.N.Y. Sept. 8, 2016) ("Rule 26's disclosure requirement is aimed at apprising a party of the witnesses on whom their opponent intends to rely to support their claims or defenses, so as to prevent unfair surprise and to give the opportunity to respond tactically.") (quotation omitted).

In light of this undisputed evidence, Plaintiffs and their experts changed the definition of "post hoc." Rather than arguing that "post hoc" analyses were those that were conducted after researchers viewed and analyzed the data, Plaintiffs' experts opined that "post hoc" analyses were analyses that were not identified in a study's protocol. (Dkt. 308-2 ¶¶ 38, 53, 56; Dkt. 308-6 ¶ 12, 33-35.) But this definition of "post hoc" is not supported by the scientific literature—a fact which Plaintiffs' experts admitted. (Dkt. 321-3; Dkt. 259-10, Sano Tr. at 195:3—197:8; Dkt. 259-11, Wittes Tr. at 88:19—91:17.)

Because Plaintiffs' characterization of the AD8 0-1 and AD8 0-2 subgroup analyses as "post hoc" has no evidentiary basis, Plaintiffs and their experts should be precluded from making such a misleading characterization at trial to avoid undue prejudice.

H. Certain of Plaintiffs' Proposed Findings of Fact Should Be Excluded Because They Constitute Legal Conclusions, Rely on Expert Testimony, are Irrelevant, or Rely on Hypotheticals

Many of Plaintiffs' proposed finding of facts in the Parties' Pre-Trial Order (Dkt. 192) constitute legal conclusions, rely on expert testimony, are irrelevant, or rely on hypotheticals. They should be excluded from trial. (Dkts. 309, 317.)

The Court ordered Plaintiffs to resubmit their proposed findings of fact by November 20, 2022. (Dkt. 317.) Defendants reserve the right to challenge these proposed findings of fact in the event Plaintiffs' new submission similarly relies on legal conclusions, hypotheticals and/or irrelevant expert testimony.

I. Certain of Defendants' Proposed Findings of Fact Should Be Admitted Because Plaintiffs Failed to Properly Contest Them With Evidence

As set forth in Defendants' pre-motion letter dated September 1, 2022 (Dkt. 309), Plaintiffs also failed to properly challenge Defendants' proposed findings of fact either because they failed to cite any evidentiary support in rebuttal, or because the evidence they cited does not, in fact,

rebut Defendants' proffered fact. (Dkt. 317.) These facts should be admitted at trial without opposition. *See Thompson v. Glob. Contacts Servs, LLC*, No. 20-CV-651, 2021 WL 3486944, at *2 (E.D.N.Y. July 21, 2021), *report and recommendation adopted*, No. 20-CV-651, 2021 WL 3476675 (E.D.N.Y. Aug. 6, 2021); *see also I.M. v. United States*, 362 F. Supp. 3d 161, 173 n.8 (S.D.N.Y. 2019).

J. There Is No Evidence To Support NYAG's NY Restitution, Disgorgement or Civil Penalty Claims

The NYAG has stated in discovery that "it will calculate its demand for restitution as the full amount of sales to New York consumers less any refunds." (Dkt. 163-5, Supp. No. 2.) But there is simply no evidence in the record reflecting "the full amount of sales to New York consumers less any refunds" and Quincy is not in possession of such information. As indicated in Quincy's interrogatory responses, the vast majority of Prevagen sales are to third-party retailers and distributors. (Dkt. 225-32, Supp. No. 1.) Except in limited cases, Defendants do not possess information sufficient to identify the number of units sold at retail by those third-party retailers and distributors, the retail prices at which such units were sold, or the gross sales revenue of such third-party retailers and distributors. (*Id.*) Moreover, when Prevagen, Inc. sells Prevagen to multi-state or national chains or other third-party retailers, it does not have direct visibility into distribution by those third party entities to store or outlets in individual states. (*Id.*) Thus, the state-specific sales information that Quincy maintains in the ordinary course of business (and which it has produced in discovery) is limited to: the number of bottles sold and shipped to addresses located in New York and the corresponding revenue associated with such sales. (*Id.*) This information includes direct-to-consumer sales to consumers with shipping addresses in New York, as well as sales to third-party retailers and distributors who may or may not ultimately sell the product to New York consumers. (*Id.*) Moreover, Quincy does not maintain state-specific

refund information. (*Id.*) As such, the New York-specific sales information that Quincy produced does not correspond with the full amount of sales to New York consumers less any refunds" and should be excluded from trial. The NYAG has proffered no evidence through fact or expert testimony to support its claim for "restitution as the full amount of sales to New York consumers less any refunds," and it should be precluded from seeking such relief at trial.

For similar reasons, the NYAG should be barred from introducing Quincy's New York-specific sales information to prove its claim for disgorgement. The NYAG has represented that "it will calculate its claim for disgorgement based on the net profits that Defendants realized from distribution of the Prevagen Products, as defined in the Plaintiffs' Complaint in this matter, in the State of New York." (Dkt. 163-5, Supp. No. 2.) In addition to there being no evidence of "the full amount of sales to New York consumers less any refunds," there is also no evidence in the record regarding "the net profits that Defendants realized from distribution of the Prevagen Products . . . in the State of New York." Accordingly, the NYAG should be precluded from seeking such relief at trial.

Finally, the NYAG has stated that "it will calculate its claim for penalties of $5000 for each violation of GBL Article 22-A." (Dkt. 163-5, Supp. No. 2.) As discussed above, the NYAG has proffered a number of different methods of calculating the number of "violations" for its civil penalty claim and also stated that it "anticipates defining each 'violation' as each deception of New York consumers in terms of each airing of a radio or television ad in the State of New York; each dissemination of a book or pamphlet advertising the Prevagen Products in the State of New York; each day on which the Prevagen Products, including the deceptive packaging claims, were available for purchase in New York retail outlets; and each day on which Quincy Bioscience advertised the Prevagen Products on a website accessible to New York consumers." (*Id.*)

Alternatively, the NYAG has suggested that "'[v]iolations' could also be defined as each sale of a Prevagen Product, such that Defendants would owe penalties of up to $5000 for each sale." (*Id.*) Because there is no evidence in the record demonstrating the number of Prevagen sales to New York consumers, and because the NYAG has failed to proffer any expert opinion regarding how such penalties can be calculated, the NYAG should be precluded from proffering this method of calculating civil penalties at trial.

K. Plaintiffs Should Be Precluded From Making Any References to, Introducing Evidence Regarding, or Eliciting Testimony About Mark Underwood or Michael Beaman's Personal Finances or Profits.

References at trial to Mark Underwood or Michael Beaman's personal finances, salaries, holdings, or other benefits allegedly received or derived from Quincy are wholly irrelevant and should be precluded. As this Court has already recognized the United States Supreme Court has held that "Section 13(b) of the Act does not authorize the FTC to seek, or the Court to award, equitable *monetary* relief, such as restitution or disgorgement" and, accordingly, "the FTC may only seek injunctive relief in this case." (Dkt. 170 (citing *AMG Cap. Mgmt., LLC v. Fed. Trade Comm'n*, 141 S. Ct. 1341 (2021).) In addition, this Court has dismissed the NYAG's claims against both Underwood and Beaman. (Dkt. 72 (dismissing the FTC and the NYAG's claims against Mr. Beaman); Dkt. 272 (dismissing NYAG's claims against Mr. Underwood).) Therefore any references to their personal finances, salaries, holdings, or other financial benefits received or derived from Quincy are wholly irrelevant and prejudicial and should be precluded.

L. Documents Produced By Third Parties In Response to Subpoenas That Did Not Comply with the Federal Rules of Civil Procedure Should Be Excluded

Plaintiffs should be excluded from introducing any information they received from third-parties in response to subpoenas that Plaintiffs issued without notice in violation of Federal Rule of Civil Procedure 45. Rule 45 requires notice and a copy of a subpoena commanding production

of documents and information be served on each party *before* it is served on the third-party. Fed. R. Civ. P. 45. Plaintiffs' exhibit list appears to include documents received from third-parties in response to a subpoena issued during this litigation to which Defendants were not provided notice. (*See, e.g.,* PX-34.) Such documents should be excluded from evidence.

CONCLUSION

Defendants are available for a conference to discuss these issues at the Court's convenience.

Respectfully submitted,

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KELLEY DRYE & WARREN LLP

By: /*s/ Geoffrey W. Castello*

John E. Villafranco (admitted *pro hac vice*)
Geoffrey W. Castello
Jaclyn M. Metzinger
Glenn T. Graham
3 World Trade Center
175 Greenwich Street
New York, NY 10007
Tel: (212) 808-7800
Fax: (212) 808-7897
jvillafranco@kelleydrye.com
gcastello@kelleydrye.com
jmetzinger@kelleydrye.com
ggraham@kelleydrye.com

Counsel for Defendants Quincy Bioscience Holding Company, Inc., Quincy Bioscience, LLC, Prevagen, Inc. d/b/a Sugar River Supplements, and Quincy Bioscience Manufacturing, LLC

COZEN O'CONNOR P.C.

By: */s/ Michael de Leeuw*

Michael de Leeuw
Tamar S. Wise
3 World Trade Center
175 Greenwich Street
New York, New York 10007
Tel: (212) 908-1331
mdeleeuw@cozen.com
twise@cozen.com

Counsel for Defendant Mark Underwood